



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 21, 2012

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No. 1043-126
DP Barcode: D399998

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang

3/21/12

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang for KPH
3/21/12

To: Velma Noble PM 31\Cletis Mixon
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Steris Corporation

FORMULATION FROM LABEL:

Active Ingredient(s):

Didecyl dimethyl ammonium chloride

Other Ingredient(s):

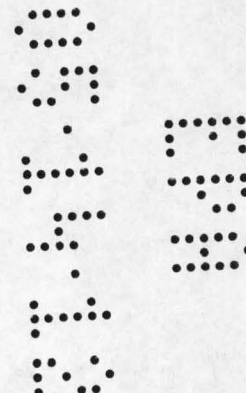
Total:

% by wt.

10.5

89.5

100.0



BACKGROUND: The registrant has submitted a response to the review done under D388063. The registrant wishes to have the acute toxicity for inhalation changed from II to III. The laboratory has submitted a clarification of the inhalation procedures used in the acute inhalation test.

RECOMMENDATIONS:

1. The acute toxicity profile for 1043-126 is:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	48412614	III	Acceptable
Acute Dermal Toxicity	48412615	IV	Acceptable
Acute Inhalation Toxicity	48412616	II	Acceptable
Primary Eye Irritation		I	Waiver
Primary Skin Irritation		I	Waiver
Dermal Sensitization	48412617	Nonsensitizer	Acceptable

2. With the clarification of the inhalation procedures, the acute toxicity profile for 1043-126 is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	48412614	III	Acceptable
Acute Dermal Toxicity	48412615	IV	Acceptable
Acute Inhalation Toxicity	48412616	III	Acceptable
Primary Eye Irritation		I	Waiver
Primary Skin Irritation		I	Waiver
Dermal Sensitization	48412617	Nonsensitizer	Acceptable

LABELING

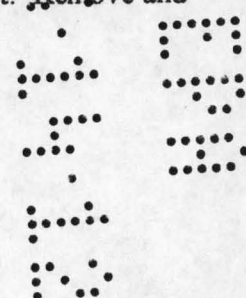
1. The signal word is **DANGER**.

2. The precautionary labeling must read, "**Corrosive**. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed or inhaled. Avoid breathing spray mist or vapor. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and natural rubber gloves. Wear goggles, face shield, or shielded safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

3. The current first aid statements must read:

If in eyes:

-Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.



If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.
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If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

4. "Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage." must appear on the label.

5. This product meets the criteria to be labeled as a Restricted-Use Pesticide based on the waivers for skin irritation and eye irritation. If regulatory does not want the product to be labeled as a Restricted-Use Pesticide, then this product must be packaged in CRP (Child-Resistant Packaging).

